Experience
responsibility

VTU engineering

GMP Compliance

Pharmaceuticals
Biotechnology
Life Sciences

- Validation of analytical methods
- Good Manufacturing Practice according to ICH Q7
- Quality by Design in accordance with ICH Q8
- Risk Management in accordance with ICH Q9 and EN ISO 14971
- Quality Management Systems and Product Life Cycle in accordance with ICH Q10 or EN ISO 13485
- ICH Q11 Development and Manufacture of Drug Substances
- FDA Guidance for Industry “Process Validation: General Principles and Practices”
- EMA Guideline on Process Validation
- EudraLex, Vol. 4 Annex 15 Qualification and Validation
- GAMP 5

Risk-based, we will jointly define customized solutions for your systems covering the entire development, planning, production and validation lifecycle.

Company Portrait

VTU Engineering is engineer and consultant for the pharmaceutical, life science and medical devices. We focus on GMP Services as part of qualification and validation of plants, processes, computer systems and medical devices.

VTU offers GMP services as part of the qualification and validation of plants, computer systems and processes and medical devices. Furthermore we offer consulting for the introduction of GMP compliant processes in engineering, production, laboratories and quality assurance and even up to collaboration during audits and inspections.

Our engineers all draw on their extensive experience to plan a wide array of projects. Through our work and constant further education in the field of pharmaceutical engineering and GMP requirements, our experts are intimately familiar with the necessities of the industry. You too can benefit from our high level of technical competence and know-how in project management.

VTU Engineering‘s sustained success since it was established in 1990 rests on two pillars.

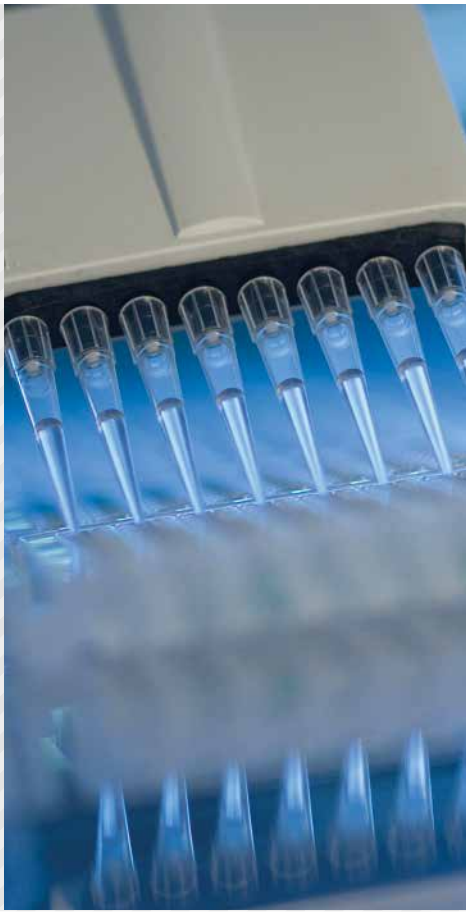
High qualified engineers

In addition to their technical know-how, VTU engineers excel through high capability for teamwork in many different project environments. Permanent training and a proven knowledge management system are a guarantee that our customers receive best expertise.

Customer orientation

The objective of the project is the objective of our work. Achieving our customers’ goals and providing solutions of excellent quality and benefit are top priorities of our project teams. Consequently, a very high percentage of our customers cooperate with VTU since many years.

Everything for your GMP Compliance!



VTU offers GMP services as part of qualification and validation for plants, computer systems and processes in the pharmaceutical industry and medical technology, as well as for the introduction of GMP-compliant processes in development, production, engineering, the control laboratory, warehousing and transport and also for successful preparation for inspections by authorities. Our expertise covers a wide area of the GxP regulated environment:

- Pharmaceutical industry/manufacture of active ingredients
- Biotechnology
- Medical technology
- Storage and transportation
- Quality control laboratory/R&D laboratory
- Hospitals/hospital pharmacies
- Blood and tissue banks

Process Validation, Quality by Design (QbD) & Continued Process Verification

We plan process validation according to the requirements of individual projects and businesses based on current legal guidelines and industry standards, and also based on our inspection experience in pre-approval inspections by national authorities for EU and FDA. Quality by Design (QbD) enables enhanced understanding of products and processes and design of the production process which promises higher quality and productivity, as well as promising low failure rates and subsequently an increase in efficiency during production. VTU provides support in QbD-based development processes and their implementation in new or existing GMP-compliant manufacturing processes in addition to the establishment of continued process verification (CPV) for new and already existing commercial processes:

- Planning and coordination of process characterization and process validation studies
- Definition of critical quality attributes (cQA) and critical process parameters (cPP)
- Drafting and moderation of process risk analyses, assessments on raw material criticality, impurity clearance, buffer stability, etc.
- Extractables/leachables assessments and design of extractables/leachables studies
- Statistical design of experiments (DoE) using a variety of software tools (SAS JMP, Umetrix Modde, Stat-Ease Design Expert and Minitab)
- Establishment and qualification of scale down models
- Validation of analytical methods
- Cleaning validation and monitoring incl. risk analyses, establishment of bracketing approaches and design, planning and reporting
- Management of process transfers incl. required risk analyses, studies and documentation
- Project and interface management

VTU engineering

VTU is a competent partner for all GMP-relevant sectors. We are very familiar with the regulations and will plan and coordinate your activities to achieve GMP compliance taking into account national requirements and including the latest developments.

Qualification and Commissioning

VTU offers GMP services for the qualification of plants in the pharmaceutical industry, starting with the production of excipients and active ingredients through to aseptic production of vaccines and parenterals. As a result of our background in design and engineering, we understand the concerns and efforts of planners, operators, and quality assurance, so we help to get them all on board together as best we can.

- Development of customized GMP qualification strategies for plants, media, rooms and laboratory equipment according to the current state of the art and regulatory requirements
- Drafting of master plans
- Establishment of tailored risk management
- Creation and moderation of risk analyses
- Creation of operator requirements
- Design review and design qualification
- IQ and monitoring of proper installation on site
- OQ and commissioning
- PQ planning and support
- Validation of computerized systems according to GAMP 5, Annex 11, CFR 211
- GMP-compliant documentation, data generation and analysis
- Storage and transport validation
- Performance of temperature mapping in temperature-controlled rooms and equipment
- Production and revision of relevant SOPs
- Delivery of training courses
- Project and interface management

QM Systems for pharmaceutical and medical products

Our experts are trained engineers, chemists and biotechnologists with years of experience in quality management systems to EN ISO 13485 and cGMP. We will advise you on the construction of your quality management systems, and review and revise your systems in preparation, among other things, for inspections.

- Construction of quality management system in accordance with GMP for drugs and EN ISO 13485 for medical devices
- Quality manual and customized SOP systems
- Qualification and validation systems
- Risk management
- Establishment of OOS/OOE procedures
- Drafting of tailor-made change or deviation management/CAPA systems
- Documentation and document control
- Delivery of GMP training courses
- Implementation of and support for self-inspections
- Preparation and support during audits, performance of supplier audits

Preparation and management of inspections by authorities

We can plan for the success of an inspection by the authorities in the form of general GMP inspections or as part of a pre-approval submission by preparing for the inspection and competently managing the inspection and inspection logistics. Thanks to our broad expertise in technology, product development and production, and GMP systems, we can provide you with excellent support during inspections by authorities.

- Consulting, GAP analyses and inspection of existing plants, process documentation and GMP systems
- Internal audits and tours with the setting of possible priorities accompanied by our trained auditors.
- Analysis and definition of key topics to be prepared
- Education and training of your experts
- Assistance when planning your inspection Logistics
- Support and attendance at your inspection

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GMP Compliance

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